***Restriction requirement***

The Examiner imposed a restriction requirement and in accordance with 37 CFR 1.142 requiring applicant to elect a single invention to which the claims must be restricted.

**1.** The Office has restricted the invention as follows:

I-XX. Claims 1-8, drawn to a method of treating 1 of 20 distinct diseases selected from the group consisting of Erectile dysfunction (I), HIV lipodystrophy (II), Fibromyalgia (III), Osteoporosis (IV), Memory disorders (V), Depression (VI), Crohn's disease (VII), Skeletal dysplasias (VIII), Traumatic brain injury (IX), Subarachnoid hemorrhage (X), Noonan's syndrome (XI), Down's syndrome (XII), Idiopathic short stature (ISS)(XHI), end stage renal disease (ESRD)(XIV), Very low birth weight (VLBW)(XV), Bone marrow stem cell rescue (XVI), Metabolic syndrome (XVII), Glucocorticoid myopathy (XVIII), Short stature due to glucocorticoid treatment in children (XDQ, and Failure of growth catching for short premature children (XX); comprising administering a compound of formula I; classified in class 424, subclass 1.69+.

XXI-XXXX. Claims 1-8, drawn to a method of treating 1 of 20 distinct diseases selected from the group consisting of Erectile dysfunction (XXI), HIV lipodystrophy (XXII), Fibromyalgia (XXIII), Osteoporosis (XXIV), Memory disorders (XXV), Depression (XVI), Crohn's disease (XVII), Skeletal dysplasias (XVIII), Traumatic brain injury (XXIX), Subarachnoid hemorrhage (XXX), Noonan's syndrome (XXXI), Down's syndrome (XXXII), Idiopathic short stature (ISS)(XXXIII), end stage renal disease (ESRD)(XXXIV), Very low birth weight (VLBW)(XXXV), Bone marrow stem cell rescue (XXXVI), Metabolic syndrome (XXXVII), Glucocorticoid myopathy (XXXIII), Short stature due to glucocorticoid treatment in children (XXXIX), and Failure of growth catching for short premature children (XXXX); comprising administering a compound of formula II; classified in class 424, subclass 1.69+.

XXXXI. Claims 9-10, drawn to a compound of formula I; classified in class 530, subclass 300+.

XXXXII. Claims 9-10, drawn to a compound of formula II; classified in class 530, subclass 300+.

2. Applicant elects group IX (traumatic brain injury administering a compound of formula I) with traverse.

The Examiner has failed to show how searching the groups I-XX together or XXIX –XXXX together creates an undue burden when all of the groups are classified in the exact same class and subclass. The Office argues the process for using the product as claimed can be practiced with another materially different product, namely method of treating 1 of 20 distinct diseases. While there are twenty conditions to be treated listed there is broad overlap between them or the conditions can be produced by the same agent. One such example is Traumatic brain injury & Subarachnoid haemorrhage where Subarachnoid haemorrhage and Traumatic brain injury are a result of brain trauma resulting in hypopitutarism (see Kreitschmann-Andermahr, I., *Pituitary* 8:219-225, 2005; Aimaretti, G., *Clin. Endocrin* 61:320-326, 2004; Urban, R., *Growth Hormone & IGF Research* 16: S25-S29, 2006; Aimaretti, G., *J. Clin Endocri & Metab* 90 6085-6092 2006; Penalver, D., *Endocrinol Nutr* 52 283-289 2005). Another example of such overlap are Very low birth weight (VLBW) & Failure of growth catching for short premature children (see Dusick, A., *Seminars in Perinatology* 4: 302-310, 2003; Hack, M., *Am. J Obstet. Gynecol.* 143: 693-699, 1982). Another such Example is Short stature due to glucocorticoid treatment in children & Glucocorticoid myopathy, which are the result of glucocorticoid treatment and both involve neuromuscular disorders.

In addition, since the product claims of Groups XXXXI and/or XXXXII are eligible for rejoinder with the process claims in accordance with the provisions of MPEP § 821.04 there can be no possible undue burden in examining them together.

Applicant requests the product claim of group XXXXI be rejoined in accordance with the provisions of MPEP 821.04, at such time when the elected product of group IX is found to be allowable.

Applicant requests reconsideration and withdrawal of the restriction requirement. Alternatively applicant requests the restriction only be maintained with respect to the compounds of Formula I and Formula II. Minimally, applicant requests

the related conditions be grouped together and the election of Traumatic brain injury (IX) be combined with Subarachnoid hemorrhage (X).

***Species Election***

3. Additionally, the Office has required applicant under 35 U.S.C. 121 to elect a single disclosed species of the elected group for prosecution on the merits as to the compound of formula I or II, applicant must elect species as to: n (e.g. 1), m (e.g. 1), and R (e.g. HGH or methionyl HGH) for preliminary examination.

4. Applicants elect the following species of Formula I, disclosed on page 52 & 53 (Example 1), wherein n=4, m=3 and R is hGH:

The elected species reads on pending claims 1-10.

**B. Information Disclosure Statement**

An Information Disclosure Statement is submitted herewith. Applicant draws the Examiner's attention to applicant's co-pending US application 10/718,340 (published as US 2004/0127417) related to the PEG-butyrylaldehyde hGH conjugate per se.

In view of the foregoing, it is respectfully submitted that all claims now pending in the present application are in condition for allowance. Therefore, passage of the application and claims to issue is respectfully requested.

Respectfully submitted,

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